

# **EXHIBIT 5**

**Summary of the Proposed Testimony of Defendants' Expert Witness, Dr. Joseph Kloepper**

**Distinction between Bacillus Genus, Species and Strains**

In biology, a "genus" is a low-level taxonomic rank (a taxon) used in the classification of living and fossil organisms.

In biology, kingdom (Latin: regnum, pl. regna) is a taxonomic rank, which is either the highest rank or in the more recent three-domain system, the rank below domain. Kingdoms are divided into smaller groups called phyla (in zoology) or divisions in botany. The complete sequence of ranks is life, domain, kingdom, phylum, class, order, family, genus, and species.

Each genus contains one or more species. Each species contains one or more strains. Each strain is genetically different than every other strain.

*Bacillus* is a genus of the family Bacillaceae, of the order Bacillales, of the class Bacilli, of the division Firmicutes, and the domain Bacteria. The genus *Bacillus* includes numerous different species, some of which include *Bacillus laterosporus*, *Bacillus licheniformis*, and *Bacillus subtilis*. The bacteria in the genus *Bacillus* are aerobic or facultative anaerobic and are gram-positive. The bacteria are also capable of producing an endospore. A person skilled in the art would recognize that term *Bacillus* to mean the bacteria that are classified under the scientific classification system in the genus *Bacillus*.

Thus, a person skilled in microbiology would understand that *Bacillus* is the name of a particular genus of bacteria; and that when the term "*Bacillus*" alone is used alone in the claims, it means any bacteria strain that has been classified as belonging within the genus called *Bacillus*.

A person skilled in microbiology would also understand that there are many different strains of *Bacillus* bacteria; and that most of the known strains have been sub-classified into different species; identified by adding a species name to the term *Bacillus*, such as *Bacillus laterosporus*.

There may be many different strains within each *Bacillus* species. A specific strain may be described by the accession number of a deposited sample of the strain in a patent depository service, as I describe below.

Consequently, a person skilled in microbiology would understand that when a particular *Bacillus* strain is named in the claims using its accession number, such as *Bacillus laterosporus* (ATCC PTA-3952), it means that particular strain and not other strains of the same *Bacillus* species.

### Endospores

An endospore is a dormant, tough, and temporarily non-reproductive structure produced by certain bacteria from the Firmicute phylum, including bacteria in the *Bacillus* genus. The endospore consists of the bacterium's DNA and part of its cytoplasm, surrounded by a very tough outer coating. The endospore can survive without nutrients, and are resistant to ultraviolet radiation, dessication, high temperatures, extreme low temperatures, and chemical disinfectants.

Because of these characteristics, the endospore is important when the bacterium is experiencing an environment that is deleterious to the usual vegetative state of the bacterium and allows the bacterium to survive. When the environmental conditions become more favorable to the vegetative state, the endospore reactivates to its vegetative state.

A person skilled in the art would understand that the term spore, as used in the patents, would mean endospore.

### American Type Culture Collection

The American Type Culture Collection (ATCC) is a private, non-profit company which maintains and distributes standard reference microorganisms, cell lines and other materials for research in the life sciences.

ATCC characterizes cell lines, bacteria, viruses, fungi and protozoa, and distributes biological materials to the public. Notably, the samples are not available to the public unless ATCC is authorized to release them.

The ATCC deposits are maintained in a live state. Samples can be obtained for a fee. The samples are maintained under unique numbers for each strain. Examples of deposit numbers are ATCC PTA-3952, ATCC PTA-3593, ATCC PTA-6175 and ATCC PTA-6174, as found in the patents.

Bacteria cells, for the most part, reproduce through cell division. The parent cell divides, forming an exact copy genetic replica of itself. For example, a facultative *Bacillus laterosporus* cell divides to produce a second cell having exactly the same genetic make-up. Therefore, a person skilled in the art would understand that a *Bacillus laterosporus* cell with an ATCC number of ATCC PTA-3952 would be a unique strain of the species *Bacillus laterosporus* and would be different genetically from a *Bacillus laterosporus* having a different ATCC number. A person of skill in the art would also recognize that colonies resulting from a reproductive culture of any specific strain of *Bacillus laterosporus* would be made up of exact genetic copies of the parent bacteria.

### Testing to Determine Plate Count

A microbiological culture, or microbial culture, is a method of multiplying microbial organisms under controlled laboratory conditions.

Microbial cultures are foundational and basic diagnostic methods used extensively as a research tool in molecular biology. It is often essential to isolate a pure culture of microorganisms. A pure (or *axenic*) culture is a population of cells or multicellular organisms growing in the absence of other species or types. A pure culture may originate from a single cell or single organism, in which case the cells are genetic clones of one another.

For the purpose of growing the microbial culture, the medium of agarose gel (Agar) is used. Agar is a gelatinous substance that is derived from seaweed. A common substitute for agar is Guar gum, which can be used for the isolation and maintenance of thermophiles. However, the agar media can be any media that provides a nutrient base for the bacteria. One example is tryptic soy.

"Plate counts" are a method of determining the concentration of viable aerobic and/or facultative bacteria within a liquid or solid. The concentrations obtained from the plate counts are given as CFU/ml (colony-forming units per milliliter) for liquids and CFU/g (colony-forming units per gram) for solids. The plate count testing method only determines the number of aerobic/facultative bacteria that are alive and capable growing and forming colonies and not the total count of bacteria present.

In practice, to determine a bacteria plate count, an agar substrate is placed in a petri dish. The substance being tested is diluted in a measured ratio with sterilized water to any number of concentration levels. The diluted substance is spread across the agar and incubated at a temperature that is conducive to the growth and cultivation of the bacteria for a period of time. The temperature need not be constant but must be within certain bounds. For most bacteria this temperature is between 0° C and 40° C. The period of time can vary. At cooler temperatures or with lower nutrient media the period is longer. At warmer temperatures or with higher nutrient media, the time period is shorter.

The aerobic and facultative bacteria will form colonies. During the period of cultivation each colony forming unit will colonize. Colonies appear visible to the naked eye as spots in the agar about the size of a pencil eraser. To derive a "plate count", the number of colonies is observed and counted. The plate count in the original substance is determined by multiplying the number of colonies observed by the ratio of the dilution of the original substance to the diluted mixture. Differences in the type of nutrient media, temperature, and cultivation time do not affect the count. The size of each colony increases with time, but the number of colonies remains constant. Therefore, a person skilled in the art would recognize that a "plate count" can be achieved with any number of methods, not just the one set out in the patents.

#### Raw Manure

A person skilled in the art would equate raw manure with fresh manure. Fresh manure is manure that has recently been excreted from the animal producing it. It has not been composted or treated in any manner to either decontaminate or reduce the pathogens or bacteria counts in it.

#### Sterilization and Decontamination

Sterilization and decontamination do not have the same meanings to someone skilled in the art. Decontamination is the reduction of the number of viable pathogen and bacteria but maintaining at least some viable bacteria while sterilization is the total elimination of viable pathogens and bacteria. A person skilled in the art would not equate sterilization with decontamination.

#### Environmental Protection Agency Regulations

The Environmental Protection Agency has provided regulations related to the use of manure as a fertilizer (EPA/625/R-92/013). The regulations require a reduction of pathogens to a level that is unlikely to pose a threat to public health. The regulations require a reduction of 2 logs in fecal coliform density. Therefore, a person skilled in the art would understand "decontamination" to mean a reduction of pathogens of at least 2 logs sufficient to meet EPA regulations.

#### Humic Acid

Humic acid is produced from the biodegradation of organic matter. It is a complex mixture of many different acids. It is naturally found in the soil and is often used as a soil supplement to help in plant growth. It is commonly recognized because of its dark brown or black coloring. A person skilled in the art would understand the term humic acid to be the result of the biodegradation of organic matter that is supplemented into the soil.